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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,147	03/17/1999	MICHEL LANQUETIN	GEI-067	1949

7590 02/05/2003

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EXAMINER
QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/284,147	LANQUETIN ET AL.	
	Examiner	Art Unit	
	Sabiha Naim Qazi	1616	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *24,25,27-30,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *24, 25, 27-30, 33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 24, 25, 27-30, 33-35 are pending and rejected.

No claim is allowed. Response and amendments filed in paper no. 25 are entered. Rejections are maintained for the following reasons. The declaration showing unexpected results must be filed under 37 CFR 1.132. Art rejections are maintained.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 24, 25, 27-30, 33-35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply.

It is unclear what is intended by "avoiding cardiovascular disease" in claim 34?

See Morton Int'l, Inc.v. Cardinal Chemical Co., 5 F.3d 1464, 1470, 28 USPQ 2d 1190, 1195 (Fed. Cir. 1993).

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 25, 27-30, 33-35 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering the combination of nomegesterol and estradiol in a continuous or intermittent fashion, from 21-25 days per month" (see lines 4-6, on page 4 of the specification), does not

reasonably provide enablement for "continuously without interruption", and "avoiding the appearance of cardiovascular disease" (see claim 34). See Conard et al. (abstract enclosed) where cardiovascular risk factors in 57 healthy postmenopausal women were studied when HRT with sequential estradiol (E2) and nomegestrol. One subject receiving 1 mg (E2) + 2.5 mg (NMA) withdrew due to headache and 1 receiving 1.5 mg (E2) + 3.75 mg withdrew because of menometrorrhagia. Note, that thses ranges are presently claimed.

The question is the unlimited time in claim. How long will be "continuous". Specification discloses i.e. 21-25 days so claims must be limited to no. of days supported by the disclosure.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Since all the showing and discussions were based on continuous administration without bleeding, the invention as claimed does not find support by the disclosure of the invention.

Claims 24, 25, 27-30, 33 and 34 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for estradiol, does not reasonably provide enablement for every estrogen such as equine conjugate estrogens, estradiol esters etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention:

The invention provides a method of treating estrogeneic deficiencies in women comprising administering without interruption combination of a 0.5 to 3 mg of an estrogenic compound and 1.5 to 3.75 mg of nomegestrol acetate.

The state of the prior art

The art does not teach various combinations of nomegestrol and estrogens in continuous manner and without interruption for certain period of time.

The predictability or unpredictability of the art

The unpredictability of the hormone art is very high. The true fact of the state of the art in the hormone and steroid area for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study.

The breadth of the claims

The claims are very broad.

The amount of direction or guidance presented

The specification provides no guidance, in the way written description, to use the invention as claimed. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result.

The significance of particular combination of estrogen and estradiol for different biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study.

The presence or absence of working examples

There are no examples or test data to support the presently claimed invention containing the combination of the any other estrogen derivatives except estradiol and nomegestrol. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The quantity of experimentation necessary

Since the nature of the method is so unpredictable, and since there is a lack of guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims. The skilled artisan, seeking lead compounds for pharmaceutical discovery, would be at a loss as to where to begin such discovery in the absence of such data.

Since the significance of particular estrogen for different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the effect of the combination of all of the estrogen derivatives with nomegestrol derivative as presently claimed.

Claims are not limited to the scope to the extent of support in disclosure so that one skilled in the art without undue experimentation can practice invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

S.Q.

SABIHA QAZI, PH.D
PRIMARY EXAMINER